K130518

APR 3 0 2013

6. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Luther NeedleSafe Products, Inc.
DATE PREPARED:	February 21, 2013
CONTACT PERSON:	Rebecca K Pine Luther NeedleSafe Products, Inc. 7 Rimani Drive Mission Viejo, CA 92692 Phone: (760) 809.5178
TRADE NAME:	Mini-Midline™ Extended Dwell Safety Catheter
COMMON NAME:	Intravascular Catheter
CLASSIFICATION NAME:	Catheter, Intravascular, Therapeutic, Short-Term, less than 30 days
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 880.5200
PRODUCT CODE	FOZ
PREDICATE DEVICES:	PowerGlide Midline Catheter (K121073) Rapid Intravascular Start System (K112347) BD Insyte Autoguard IV Catheter (K110443)

Substantially Equivalent To:
The Mini-Midline Extended Dwell Safety Catheter is substantially equivalent in intended use, principal of operation and technological characteristics to the PowerGlide Midline Catheter, Rapid Intravascular Start System and the BD Insyte Autoguard IV Catheter.

Description of the Device Subject to Premarket Notification:
The Mini-Midline Extended Dwell Safety Catheter is a sterile, single use device designed to provide access to the patient's vascular system. The device provides peripheral vascular access and administration of fluids, medications and nutritional therapy as prescribed. The device consists of an introducer needle, passive safety mechanism and single lumen catheter. The Mini-Midline Extended Dwell Safety Catheter is 20 gauge.

Indication for Use:
The Mini-Midline™ Extended Dwell Safety Catheter is inserted into a patient's vascular system for short term use (< 30 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.

Technical Characteristics:
The Mini-Midline™ Extended Dwell Safety Catheter has similar physical and technical characteristics to the predicate devices as shown in the table below.

	Mini-Midline™ Extended Dwell Safety Catheter	PowerGlide Midline Catheter (K121073)	Rapid Intravascular Start System (K112347)	BD Insyte Autoguard IV Catheter (K110443)
Function	Intravenous catheter	SAME	SAME	SAME
Anatomical Site	Peripheral vasculature	SAME	SAME	SAME
Duration of use	< 30 days	SAME	SAME	SAME
Access method	Venipuncture, via needle	SAME	SAME	SAME
Catheter Gauge	20	20	22 20 18	14 16 18 20 22 24
Sharps injury prevention feature	Yes	SAME	SAME	SAME
How provided	Sterile, disposable (single use)	SAME	SAME	SAME

Performance Data:
All necessary verification and validation testing has been performed for the Mini-Midline™ Extended Dwell Safety Catheter to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Testing included:

- Visual Inspection
- Leak Testing
- Flow Rate Testing
- Tensile Strength
- Corrosion Resistance
- Flexural Integrity
- Insertion Force
- User Evaluation (simulated use)

Basis for Determination of Substantial Equivalence:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Mini-Midline™ Extended Dwell Safety Catheter is determined by Luther NeedleSafe Products, Inc. to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 30, 2013

Ms. Rebecca K. Pine
Luther NeedleSafe Products, Incorporated
7 Rimani Drive
MISSION VIEJO, CA 92692

Re: K130518
Trade/Device Name: Mini-Midline™ Extended Dwell Safety Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 22, 2013
Received: March 1, 2013

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

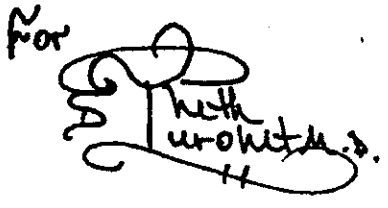
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130518

Device Name: **Mini-Midline™ Extended Dwell Safety Catheter**

Indications for Use:

The Mini-Midline™ Extended Dwell Safety Catheter is inserted into a patient's vascular system for short term use (< 30 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure.

AND/OR

Prescription Use __X__ (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2013.04.30 11:56:57 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130518